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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,988	11/13/2003	Leslie W. Organ	50162-042	6765
<div>7590 04/12/2007 McDermott, Will & Emery 600 13th Street, N.W. Washington, DC 20005-3096</div>			<div>EXAMINER NGUYEN, HUONG Q</div> <div>ART UNIT 3736 PAPER NUMBER</div>	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/705,988

Applicant(s)

ORGAN ET AL.

Examiner

Helen Nguyen

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 59-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/13/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group IX corresponding to **Claims 65-68** in the reply filed on 1/3/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-58 and 73-125 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/3/200. Amendment of Claims 59 and 69 such that Claims 59-64 and 69-72 now depend from Claim 65 is acknowledged and discussed below. Claims 59-72 remain pending.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

Art Unit: 3736

5. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09749613, filed 12/28/2000, now US Pat No. 6768921. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR

Art Unit: 3736

1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 11/13/2003 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

7. However, it is noted that the foreign reference and NPL submitted on the IDS have **NOT** been considered because applicant has failed to submit a copy of said references as required by CFR 1.98.

Drawings

8. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the gap of **Claim 62** positioned with respect to the adjacent selected conducting surfaces of the connector so that the continuous conductive path does not extend directly therebetween and the alignment means of **Claim 70** must be clearly shown, i.e. with reference numbers, or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

9. **Claims 59-72** are objected to because of the following informalities:

Regarding **Claim 65**, step b) should read “two selected conducting surfaceS.”

Regarding **Claim 59**, it is believed that “that” of “the connector *that* electrically links the electrode array” was inadvertently left in and should be deleted to maintain claim language comprehension.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **Claims 59-72** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the method of confirming an operable electrical contact as recited in **Claims 65-68** has not been clearly disclosed in the specification to reasonably convey to one skilled in the art that the inventors at the time of filing had possession of the claimed invention. Where in the specification is this method disclosed? Applicant is requested to point out sections of the specification that clearly disclose said method.

Art Unit: 3736

12. Furthermore, the specification does not clearly disclose the methods recited in **Claims 59-64 and Claims 69-72** as performed in the sequential order of after said aforementioned method of confirming operable electrical contact of Claims 65-68, as required by applicant's amendment of the dependency of Claims 59-64 and 69-72, thus bringing to question the possession of said claimed invention by the inventors at the time of filing. Once again, if this is untrue, applicant is requested to point out sections of the specification that clearly disclose said method steps as recited in the amended claims.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

14. **Claims 62-64 and 70-72** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding **Claim 62**, it is not understood what is meant by a gap in the spacing of the unlinked conducting surfaces of the electrode array and how it may be positioned with respect to the adjacent selected conducting surfaces of the conductor so that the continuous conductive path does not extend directly therebetween. Where is this gap located? Regarding **Claim 70**, it is not understood what the alignment means comprises. Where is this alignment means located? Applicant is respectfully requested to point out said gap and alignment means in the drawings. Please see the drawing objections above.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. **Claims 59-68** are rejected under 35 U.S.C. 103(a) as being unpatentable over House, Sr. (US Pat No. 4660562) in view of Church et al (US Pat No. 5277197).

17. In regards to **Claim 65**, House, Sr discloses a method of forming an operable electrical contact between a plurality of spaced unlinked conducting surfaces (30,32,34,36) of an electrode array (10) best seen in Figures 3-4 and a plurality of spaced unlinked conducting surfaces (78,80,82,84) of a connector (22) best seen in Figure 6, the method comprising: a) placing the electrode array and connector in electrical contact with respect to one another by overlapping the spaced unlinked conductive surfaces of the electrode array with the spaced unlinked conductive surfaces of the connector to form a continuous conductive path between two selected conducting surfaces (Col.2: 29-34; Col.3: 36-51; Col.4: 62-68).

18. However, House, Sr does not disclose measuring a test signal over the conductive path between the two selected conducting surfaces to see if an operable electrical contact has been established. Church et al teach measuring a test signal over a conductive path between two selected conducting surfaces to see if an operable electrical contact has been established (Col.9: 16-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of House, Sr. to include the step of measuring a test signal over the conductive path between the two selected conducting surfaces to see if an

Art Unit: 3736

operable electrical contact has been established, as taught by Church et al, for proper confirmation of electrical contact.

19. In regards to **Claim 66**, House, Sr discloses the conductive path is a ground conductive path.

20. In regards to **Claim 67**, Church et al disclose electrical resistance is measured and compared to a pre-established value for an operable electrical contact (Col.9: 16-24).

21. In regards to **Claim 68**, House, Sr in combination with Church et al disclose placing the electrode array and connector in electrical contact with respect to one another places respective terminals (30,32,34,36) for electrodes of the electrode array into electrical contact with respective conductive surfaces (78,80,82,84) of the connector and the test establishes whether proper electrical contact between the respective terminals and conductive surfaces has been established.

22. In regards to **Claim 59**, House, Sr discloses the number of connections in the conductive path of the electrode array is minimized to two (Col.1: 55-56) capable of diagnosing the presence of a disease state in a living organism and the connector (22) electrically links the electrode array (10) to an electronic module (28) best seen in Figure 6.

23. In regards to **Claim 60**, House, Sr discloses the spaced unlinked conducting surfaces (30,32,34,36) on the electrode array are spaced generally around an opening (20, 68, 66) provided by the array best seen in Figure 1 and 5, and the spaced unlinked conducting surfaces

Art Unit: 3736

(78,80,82,84) on the connector are spaced around a similar opening provided by the connector, best seen in Figure 6.

24. In regards to **Claim 61**, House, Sr discloses the two selected conducting surfaces of the connector (22) are adjacent to one another, best seen in Figure 6.

25. In regards to **Claim 62**, House, Sr discloses a gap is provided in the spacing of the unlinked conducting surfaces (30,32,34,36) of the electrode array best seen in Figures 3-4 so that when the electrode array and connector (22) are placed in overlapping relation the gap is positioned with respect to the adjacent selected conducting surfaces (78,80,82,84) of the connector so that the continuous conductive path does not extend directly therebetween.

26. In regards to **Claim 63**, House, Sr discloses an alignment means (38, 40) is provided to ensure that the electrode array (10) and connector (22) overlies to form a continuous conductive path between the two selected conducting surfaces (Col.3: 51-54), best seen in Figures 1 and 6.

27. In regards to **Claim 64**, House, Sr discloses the conductive path is a ground conductive path.

28. **Claims 69-72** are rejected under 35 U.S.C. 103(a) as being unpatentable over House, Sr in view of Church et al, further in view of Faupel et al (US Pat No. 5660177) and Corasanti (US Pat No. 3841312).

Art Unit: 3736

29. In regards to **Claim 69**, House, Sr in combination with Church et al disclose the method above but do not disclose the method further comprising the step of diagnosing the presence of a disease state in a living organism from a plurality of electrode array elements, wherein each electrode array element comprises a body having at least one arm extending from the body with at least one electrode provided on the arm, the step of diagnosing comprising: a) overlying the plurality of electrode array elements at the respective bodies thereof to form a main body of the electrode array with the arms of the respective electrode array elements extending from the main body in spaced relation; and b) clamping the plurality of electrode array elements together.

30. Faupel et al disclose electrode array elements for diagnosing the presence of a disease state in a living organism, the electrode array elements (176) comprising a body (194) having at least one arm (192) extending from the body with at least one electrode (106) provided on the arm, best seen in Figure 11, wherein the structure of said electrode array enables ease of positioning on the surface of a living organism for disease diagnosis (Col.18: 62-65).

31. Corasanti discloses a method overlying a plurality of electrode elements at the respective bodies thereof to form a main body and clamping the plurality of electrode elements together, best seen in Figures 6-10, to provide an effective electrode arrangement that promotes better contact between the surface of the living organism and the electrode (Col.4: 15-55).

32. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of House, Sr and Church et al to include the steps of overlying a plurality of electrode array elements at the respective bodies thereof to form a main body of the electrode array and clamping the plurality of electrode elements together, wherein each electrode array element comprises a body having at least one arm extending from the body

Art Unit: 3736

with at least one electrode provided on the arm such that when in the overlying state, the arms of the respective electrode array elements extend from the main body in spaced relation, as taught by Faupel et al and Corasanti respectively, to provide a superior electrode arrangement designed to ease positioning on the surface of the living organism as well as maintain close contact between the surface of the living organism and the electrode array.

33. In regards to **Claim 70**, Faupel et al disclose alignment means is provided to ensure that the arms (192) of the respective electrode array elements (176) extend around the main body (194) of the electrode array in spaced relation, best seen in Figure 11.

34. In regards to **Claim 71**, Corasanti discloses a retaining member (42) is used in clamping the plurality of electrode array elements together, best seen in Figures 3-9, and the retaining member comprises a stiffening member adapted to flatten part of the tissue of the living organism being diagnosed (Col.3: 66-68, Col.4: 1-5).

35. In regards to **Claim 72**, Corasanti discloses the stiffening member (42) is in the form of a ring, best seen in Figure 4.

Conclusion

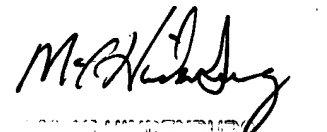
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

Art Unit: 3736

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
3/27/2007



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